Selectra Accessory Kit

SEP 2 6 2011

Special 510(k) Premarket Notification

1. 510(K) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	Selectra Accessory Kit
Classification:	Class II (21 CFR 870.1330; 870.1340; 870.4500; 880.5860)
Classification Name:	Cardiovascular surgical instruments, catheter guide wire, catheter introducer, piston syringe
Product Code:	DWS, DQX, DYB, FMF

General Description:

The Selectra accessory kit includes a variety of commonly used catheter accessories which are combined in a single package.

The **Selectra accessory kit** includes the following components:

- 1 Selectra Slitter Tool
- 1 Seldinger Guide Wire
- 4 Transvalvular Insertion (TVI) Tools
- 1 Syringe
- 1 Torquer
- 2 Stopcocks
- 2 Check valves
- 2 Sealing caps
- 1 Technical Manual

The Selectra accessory kit may be used with the Selectra CS lead introducer system, BIOTRONIK's family of guiding catheters specifically used for the placement of coronary sinus leads. The Selectra accessory kit is the subject of this Special 510(k).

Device Modification:

The changes made to the Selectra accessory kit, as compared to the previously cleared ScoutPro ACS accessory kit, primarily include minor component modifications.

The usage of the Selectra accessory kit remains unchanged and the product characteristics, such as indications for use, contraindications, and function, are the same as the ScoutPro ACS accessory kit cleared on July 23, 2010 (K101776). Therefore, this previously cleared accessory kit will serve as the predicate device for the modified accessory kit included in this Special 510(k).

Predicate Device:

BIOTRONIK's ScoutPro ACS Accessory Kit (K101776)

Indication for Use:

The Selectra accessory kit is used in conjunction with the Selectra CS lead introducer system to facilitate lead implantation in the left side of the heart via the coronary sinus.

Name and Address of Manufacturer:	BIOTRONIK SE & Co. KG (reg. no. 9610139) Woermannkehre 1, 12359 Berlin, Germany 011-49-30-689-05-1210
Name and Address of Contract Manufacturer:	BIOTRONIK AG (reg. no. 8043892) Ackerstrasse 6 8180 Bülach, Switzerland 011-41-44-864-5169
Name and Address of Contract Sterilizer:	Sterigenics Germany GmbH (reg. no. 3002807090) Kasteler Straße 45 (Rheingaustrasse 190 – 196) D-65203 Wiesbaden, Germany
Contact Person(s) and Phone Number:	Jon Brumbaugh VP, Regulatory Affairs and Compliance Phone (888) 345-0374 Fax (503) 635-9936 jon.brumbaugh@biotronik.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
Biotronik, Inc.
6024 Jean Road
Lake Oswego, Oregon 97035

SEP 26 2011

Re: K111839
Trade/Device Name: Selectra Accessory Kit
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide wire
Regulatory Class: Class II
Product Code: DQY, DQX
Dated: June 28, 2011
Received: June 29, 2011

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: Selectra CS Lead Introducer System
Indications for Use:

The Selectra accessory kit is used in conjunction with the Selectra CS lead introducer system to facilitate lead implantation in the left side of the heart via the coronary sinus.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111839